BY HAND

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Gelfand et al.

Serial No.: 07/873,897 Art Unit: 1651

Filed: April 24,1992 Examiner: D. Naff

For: PURIFIED THERMOSTABLE ENZYME

PETITION UNDER 37 C.F.R. § 1.183

Box DAC
Assistant Commissioner for Patents
Crystal Park One, Suite 520
Washington, D.C. 20231

Sir:

Applicants respectfully petition under 37 C.F.R. § 1.183 to suspend or waive the requirements of 37 C.F.R. § 1.97 so that the Second Supplemental Information Disclosure Statement filed October 7, 1999 (the "October 1999 IDS") may be considered and entered by the Examiner in connection with the presently pending captioned application. Applicants request suspension of the rules in this situation because, as detailed below, the captioned application presents a special situation. The captioned application was on appeal from 1993 until a decision reversing the examiner was rendered on July 30, 1999. During this lengthy appeal, allegedly relevant materials were brought to Applicants' attention in connection with proceedings in foreign counterpart applications and litigation of a patent issuing from a related application, all of which have been reviewed in connection with the captioned application and, for the reasons detailed in the October 1999 IDS, are either cumulative to, or less relevant than, the references already of record. However, since the patent issuing from the captioned application will almost certainly be enforced against would be infringers,

Applicants would like to make the cited materials of record to foreclose any allegations that Applicants in any way intended to withhold material information from the Patent Office.

But, also during the lengthy appeal, the rules governing the calculation of patent term changed dramatically, effectively denying Applicants the opportunity to have the October 1999 IDS entered and considered without forfeiting considerable patent term. Under Rule 97, to have the October 1999 IDS entered, Applicants would have to file a continuation of the captioned application and incur a loss of at least ten years of valuable patent term. Because Applicants appealed (and won reversal of) the Examiner's final rejection, Applicants cannot avail themselves of the transitional provision 37 C.F.R. § 1.129(a) designed, *inter alia*, to allow an applicant of an application pending for more than two years prior to June 8, 1995, such as the captioned application, to have an Information Disclosure Statement entered without surrendering valuable patent term. Since Applicants are in such an exceptional situation, Applicants respectfully request that the provisions of 37 C.F.R. § 1.97 be waived in this instance so that the October 1999 IDS may be considered and entered.

In particular, Applicants filed a Notice of Appeal on August 19, 1993 to appeal the Examiner's final rejection dated March 19, 1993. Applicants finally received a decision from the Board of Patent Appeals and Interferences on July 30, 1999, almost six years later, reversing the Examiner's final rejection. As discussed in detail in the October 1999 IDS, while this application was on appeal, foreign counterparts of the captioned application have been the subjects of proceedings in Australia, Europe and Japan. During these proceedings, many of the references cited in the October 1999 IDS were alleged to be relevant to claims similar to those pending in the present application. The cited references have been reviewed in connection with the captioned application, and, for the reasons discussed in detail in the October 1999 IDS, it is believed that these references fall outside the scope of material information for which there is a duty of disclosure under 37 C.F.R. § 1.56,

because these references are either cumulative to, or are less relevant than, the references already of record in the captioned application.

Also while this case was on appeal, the Assignee and some of the Applicants of the captioned application have been engaged in defending against inequitable conduct allegations that have been made in the litigation of United States patent No. 4,889,818 (the "'818 patent"),[1] which issued from application Serial No. 07/069,509, filed June 17, 1987, of which the grandparent of the captioned application is a continuation-in-part application.[2] As set forth in the October 1999 IDS and the materials submitted therewith, the claims of the '818 patent relate to a purified, thermostable DNA polymerase from *Thermus aquaticus*, both the native and recombinant forms, and the inequitable conduct allegations against the '818 patent are not believed to be relevant to the patentability of the subject matter claimed in the instant application.

Nevertheless, because there is a likelihood that any patent issuing on the above-captioned application will be asserted against infringers, and having had the experience in the litigation of the '818 patent of being subjected to numerous, spurious inequitable conduct allegations, it is out of an abundance of caution and desire to foreclose any allegations that Applicants or their representatives, in any way, intended to withhold material information from the Patent Office, that Applicants and their Assignee respectfully seek to have the October 1999 IDS and the references cited therein, which are not believed to be material, be made of record in the captioned application.

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1 The litigation is currently pending in the Northern District of California, *Hoffmann-LaRoche Inc. and Roche Molecular Systems, Inc. v. Promega Corporation*, Civil Action No. C-93-1748 VRW. The parties are presently awaiting a decision of the Court after a trial on inequitable conduct which took place in February, 1999.

2 The present application is a file wrapper continuation of application Serial No. 07/387,003, filed July 28, 1989, which is a divisional of application Serial No. 07/143,441, filed January 12, 1988, which is a continuation-in-part of application Serial No. 07/063,509, filed June 17, 1987, which issued as the '818 patent.

However, since the mailing of a Final Office Action in connection with the captioned application occurred on March 19, 1993, and since Applicants are unable to make the Certification Under 37 C.F.R. § 1.97(e), as required by 37 C.F.R. § 1.97(c), Applicants recognize that, pursuant to Rule 97, the Patent and Trademark Office is not required to make the October 1999 IDS of record. In fact, in a telephonic communication with the undersigned, Director Doll indicated that, indeed, the Examiner would not enter the October 1999 IDS into the record.

Applicants are, consequently, petitioning to waive the requirements of Rule 97. According to 37 C.F.R. § 1.183, "[i]n an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived...." (emphasis added). This is such an extraordinary situation. During the six year appeal from the Examiner's unjustified (as determined by the Board) final rejection, as discussed above, the materials cited in the October 1999 IDS were brought to Applicants' attention and, by the time a decision was rendered in the appeal, the rules for calculating patent term had been changed, making the re-filing of an application potentially very costly in patent term.

Specifically, the present application was filed on April 24, 1992; thus, according to 35 U.S.C. § 154(c), the patent issuing from this application will be entitled to a term of seventeen years from the issue date, as would any continuation of the present application filed prior to June 8, 1995. The present application claims priority under 37 U.S.C. § 120 to, *inter alia*, application Serial No. 07/063,509, filed June 17, 1987. Under 35 U.S.C. § 154(a), any continuation application of the captioned application would have a term of 20 years from the earliest claimed priority date, *i.e,* would expire in the year 2007. Accordingly, filing a continuation application of the captioned application at this time would result in a very significant loss of patent term, *i.e.*, at least ten years. Due to the unusual

exigencies of the captioned application, it is not fair to require Applicants to pay such a hefty price – more than a decade of patent term – to have the October 1999 IDS entered.

Moreover, because Applicant appealed the Examiner's rejection in 1993, Applicants cannot now take advantage of the transitional provisions of 37 C.F.R. § 1.129(a) – the very provisions designed to mitigate just such a burden (see Manual of Patent Examining Procedure §706.07(g) (Seventh Edition, July 1998)). And, if Applicants were to file a continuation of the captioned application, they would be unable to avail themselves of the term extension provisions of 35 U.S.C. § 154(b)(2) to recoup even a small portion of the lost term, since the appeal would not have been taken in the continuation application. It seems entirely unjust that actions taken in an abundance of caution to comply with the duty of candor should carry such a stiff penalty, *i.e.*, the loss of a decade or more of patent term.

Applicants submit that, because of the unjustified final rejection, the lengthy appeal and the "pre-GATT" status of the present application, they are in a special situation that warrants a waiver of the restrictions of 37 C.F.R. § 1.97. Accordingly, Applicants respectfully request that, in this unique situation, the provisions of 37 C.F.R. § 1.97 be suspended or waived, and the October 1999 IDS be considered and entered.

Pursuant to 37 C.F.R. § 1.183, the petition fee under 37 C.F.R. § 1.17(h), estimated to be $130.00, is submitted herewith.

Respectfully submitted,

Date: December 6, 1999

Jennifer Gordon 30,753
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Enclosures

by Margaret B. Boudreau
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BY HAND

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#43

Application of: Gelfand et al.

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FEE TRANSMITTAL SHEET

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Box DAC
Assistant Commissioner for Patents
Crystal Park One, Suite 520
Washington, D.C. 20231

Sir:

The fee required to be filed in connection with the accompanying Petition Under 37 C.F.R. § 1.183 for the above-identified application, pursuant to 37 C.F.R. § 1.17(h), has been estimated to be $130.00. Please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150. A duplicate of this sheet is enclosed for accounting purposes.

Respectfully submitted,

Date: December 6, 1999

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Enclosures